

**BD-STEPS  
TELEPHONE SCRIPTS**

**Saliva Collection Reminder Call 1 to Case or Control Mother**

Timing of Saliva Collection Reminder Call 1: 14 days after Date of Saliva Collection Kit Mailing  
Place Call 2 if kit not returned 14 days after either phone contact or saliva reminder letter is sent.

**Saliva Collection Reminder Call 1 to Mother**

Hello, may I speak to <Mother>? This is <Interviewer> calling for the Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS. <Mother>, recently we sent you a saliva (or spit) collection kit. Did you receive that?

**NO** If it's all right, I can send you one more kit. I am only able to send one replacement kit, so would you please confirm that I have the correct address to send this kit?  
[VERIFY ADDRESS. DESCRIBE KIT, PROBE AS APPROPRIATE.]  
If you have any questions about the consent forms or about how to do the kit, you may call our toll-free number.  
<TBD toll-free number>. We'd be happy to "walk you through" the kit.

**YES** I am calling today to find out if you have any questions or problems with collecting the samples. We know there is a lot of information given in the consent forms and instructions. I'd be happy to answer any questions that you have, or to "walk you through" the kit. Do you have any questions?

**NO** [DESCRIBE KIT. PROBE AS APPROPRIATE.]  
When could we expect to receive the saliva samples?  
If you have any questions about the consent forms or about how to do the collection, you may call our toll-free number <TBD toll-free number>. .

**YES** [ANSWER QUESTIONS. DESCRIBE KIT, PROBE AS APPROPRIATE.]  
When could we expect to receive the saliva samples?  
If you have any questions about the consent forms or about how to do the collection, you may call our toll-free number <TBD toll-free number>.

**IF REFUSAL: DO NOT ASK OR PROBE FOR REASONS.**  
RECORD REASON FOR REFUSALS ONLY IF THE SUBJECT OFFERS THIS INFORMATION.

**Thank you.**

**MESSAGE FOR SUBJECT'S ANSWERING MACHINE:**

"We're calling <SUBJECT'S FIRST/LAST NAME> to see if you received the kit we sent in the mail. You may call us at our toll-free number, <TBD toll-free number> with any questions. We'll also try calling you again."

**MESSAGE LEFT WITH ANOTHER PERSON:**

"We're calling <SUBJECT'S FIRST/LAST NAME> to see if she received the kit we sent in the mail. She may call us at our toll-free number <TBD toll-free number> with any questions. We'll also try calling her again. (When would be a good time to reach her?)"

## **PROBES FOR Saliva Collection Kit:**

PROBE: Do you have a minute to hear about the kit?

**IF YES** (IF MOTHER HAS TIME, DESCRIBE KIT):

The kit includes collection containers in clear plastic cases. The collection container for you and your baby's father is a tube with an attached funnel and cap (one for each of you that is clearly marked MOTHER or FATHER). <IF INFANT IS ALIVE: The collection container for your baby is a round disc consisting of a base and cap (similar to a contact lens case). There should also be a packet that contains a pair of blunt tip scissors and a plastic bag with 5 small sponges on plastic handles.> A plastic bag with a small square of absorbent cloth is included for each of the collection devices. We also included detailed instructions on how to collect the samples and consent forms for you to sign and return with the samples in a postage-paid envelope.

PROBE: If you have any questions about the consent forms or about how to collect the samples, you may call our toll-free number <TBD toll-free number>. If you'd like, I can go through the consent forms and instructions with you over the phone.

PROBE: We know there is a lot of information given in the consent forms and instructions.

Do you have any questions about the consent forms or the instructions?

OR, are there any parts that were not clear?

OR, is there anything I can help you with?

PROBE: If you'd like, I could go through the consent forms/instructions with you over the phone.

I could stay on the line while you collect the samples.

I could stay on the line now, or we could schedule a time that is convenient for you.

PROBE: Some people have concerns about confidentiality, privacy, or genetic testing. Do you have concerns about confidentiality, privacy, or genetic testing?

**IF YES:**

[INTERVIEWER SHOULD REFER TO QUESTION AND ANSWER SECTION AT THE END OF THIS DOCUMENT OR THE SALIVA COLLECTION FAQ SHEET FOR RESPONSE OPTIONS TO COMMON QUESTIONS]

**BD-STEPS  
TELEPHONE SCRIPTS**

**Saliva Collection Reminder Call 2 to Case or Control Mother**

Timing of Call #2: 14 days after Date of “Completed” First Saliva Reminder Call (or Letter)

**Saliva Collection Reminder Call 2 to Mother**

Hello, may I speak to <Mother>? This is <Interviewer> calling for the Birth Defects Study To Evaluate Pregnancy exposureS or BD-STEPS. <Mother>, I recently checked our records and noted that we sent a saliva collection kit to you on <Date Sent>. [IF MAILED A REPLACEMENT KIT: Did you receive that kit?] We have not received your saliva (spit) samples and I am calling today to find out if you had any questions or problems collecting the sample(s). We know there is a lot of information given in the consent forms and instructions. I’d be happy to answer your questions, or to “walk you through” the kit. Do you have any questions?

**NO (NOT RECEIVE KIT OR NO QUESTIONS):**

VERIFY ADDRESS. DESCRIBE KIT, PROBE AS APPROPRIATE.

[IF SECOND KIT NOT RECEIVED, **DO NOT** REMAIL A THIRD KIT]

When could we expect to receive the saliva samples?

If you have any questions about the consent forms or about how to complete the collection, you may call our toll-free number (**TBD toll-free number**).

**YES (HAS QUESTIONS)**

INTERVIEWER SHOULD REFER TO QUESTION AND ANSWER SECTION AT THE END OF THIS DOCUMENT OR THE SALIVA COLLECTION FAQ SHEET FOR RESPONSE OPTIONS TO COMMON QUESTIONS; DESCRIBE KIT, PROBE AS APPROPRIATE.

When could we expect to receive the saliva samples?

If you have any questions about how to collect the samples or about the consent forms, you may call our toll-free number **TBD toll-free number**.

**IF REFUSAL: DO NOT ASK OR PROBE FOR REASONS.**

RECORD REASON FOR REFUSALS ONLY IF THE SUBJECT OFFERS THIS INFORMATION.

**Thank you.**

**MESSAGE FOR SUBJECT’S ANSWERING MACHINE:**

“We’re calling <SUBJECT’S FIRST/LAST NAME> to see if you received the kit we sent in the mail. You may call us at our toll-free number **TBD toll-free number** with any questions. We’ll also try calling you again.”

**MESSAGE LEFT WITH ANOTHER PERSON:**

“We’re calling <SUBJECT’S FIRST/LAST NAME> to see if she received the kit we sent in the mail. She may call us at our toll-free number **TBD toll-free number** with any questions. We’ll also try calling her again. (When would be a good time to reach her?)”

**BIRTH DEFECTS STUDY TO EVALUATE PREGNANCY EXPOSURES (BD-STEPS)**

**ADDRESS CORRECTION FORM FOR SALIVA COLLECTION FOLLOW-UP CALLS**

USE FOLLOWING FOR NOTES. THEN, RECORD UPDATED INFORMATION IN SALIVA COLLECTION TRACKING SYSTEM. NOTE IN COMMENTS IF MOM AND DAD LIVE SEPARATELY.

**CORRECTED ADDRESS—MOTHER:**

STREET: \_\_\_\_\_  
APARTMENT: \_\_\_\_\_  
CITY: \_\_\_\_\_  
STATE: \_\_\_\_\_ ZIPCODE: \_\_\_\_\_

**CHILD LIVES WITH:**

BOTH PARENTS \_\_\_\_\_ MOTHER ONLY \_\_\_\_\_ FATHER ONLY \_\_\_\_\_  
OTHER (SPECIFY): \_\_\_\_\_

**CORRECTED ADDRESS—CHILD (IF DIFFERENT FROM PARENTS):**

STREET: \_\_\_\_\_  
APARTMENT: \_\_\_\_\_  
CITY: \_\_\_\_\_  
STATE: \_\_\_\_\_ ZIPCODE: \_\_\_\_\_

\_\_\_ **MOTHER REFUSED ENTIRE KIT; REQUESTED DO NOT SEND KIT.**

REASON (IF OFFERED): \_\_\_\_\_

\_\_\_ **MOTHER REFUSED PART OF KIT; DO NOT SEND KIT TO:**

MOTHER \_\_\_\_\_ CHILD \_\_\_\_\_ FATHER \_\_\_\_\_  
REASON (IF OFFERED): \_\_\_\_\_

\_\_\_ **MOTHER NEEDS ADDITIONAL KIT OR PART OF KIT:**

If YES SPECIFY: Full Kit \_\_\_\_\_ Consent Form \_\_\_\_\_ Collection Devices \_\_\_\_\_

## **BD-STEPS**

### **Saliva Collection Reminder Calls to Case or Control Mother**

#### **TELEPHONE SCRIPTS FOR ANSWERING QUESTIONS ABOUT SALIVA COLLECTION KITS**

**IF MOTHER ASKS QUESTIONS ABOUT THE SALIVA COLLECTION KITS,  
BUT HAS NOT RECEIVED THE LETTER YET, SAY:**

**I'd be happy to answer any of your questions now, but you might find it more helpful if you wait to see the kit. The kit comes with specific instructions and explains this part of the study, including confidentiality of the samples. You can call us back at that time if you still have questions.**

**DESCRIBE KIT, IF MOTHER WANTS MORE INFORMATION:**

The kit includes collection containers in clear plastic cases. The collection container for you and your baby's father is a tube with an attached funnel and cap (one for each of you that is clearly marked MOTHER or FATHER). <IF INFANT IS LIVING: The collection container for your baby is a round disc consisting of a base and cap (similar to a contact lens case). There should also be a packet that contains a pair of blunt tip scissors and a plastic bag with 5 small sponges on blue handles. > A plastic bag with a small square of absorbent cloth is included for each of the collection devices. We also included detailed instructions on how to collect the samples and consent forms for you to sign and return with the samples in a postage-paid envelope.

If you have any questions about how to complete the collection or about the consent forms, you may call our toll-free number **TBD toll-free number**. We can go through the consent forms and instructions with you over the phone.

**IF SUBJECT NEEDS ANOTHER SALIVA COLLECTION KIT  
(NOT RECEIVED OR LOST KIT): ONLY 1 ADDITIONAL KIT WILL BE MAILED TO EACH  
FAMILY**

I am only able to send one replacement kit, so would you please confirm your complete mailing address address for sending this kit? Do you have an apartment number? (VERIFY ADDRESS AGAINST ADDRESS IN FILES.)

**IF SUBJECT ASKS FOR A REPLACEMENT SALIVA COLLECTION KIT, and SHE HAS  
ALREADY BEEN MAILED ONE REPLACEMENT:**

Thank you for your interest in the study but we are only able to mail one replacement kit. I apologize that the other kits were not received.

## COMMON QUESTIONS AND ANSWERS –SALIVA COLLECTION

### WHY PROVIDE SAMPLES?

**Purpose of samples:** These samples will be used to study genetic (inherited) factors that may play a role in why some babies have birth defects. They will only be used to study birth defects and for no other purpose.

**Importance of participating:** This study may result in a better understanding of the causes of birth defects.

**We Need Many People to Participate:** To study genes, we need a lot of families to send in their samples. Because of this, your samples may be stored for many years before we have samples from enough families to complete studies of genetic factors. (We have no plans to ever destroy these samples.)

### PROCEDURES FOR COLLECTING SAMPLES:

**“How are samples collected?”** Saliva samples are collected from your child by rubbing the inside of his/her cheek with soft sponges and cutting the sponges off into a collection container. Saliva samples are collected from each parent by spitting into a funnel connected to a small collection tube. You will also need to sign the written consent form. The samples and consent forms should be returned in the enclosed pre-addressed stamped envelope. (All materials are provided. You will receive written instructions with pictures that show how to collect the samples.)

**“Will a cold or illness affect the samples?”** No, being sick won’t affect the quality of the saliva samples. You can collect a sample even when a person is sick. (OR: You don’t have to be healthy; you don’t have to be germ-free or virus-free.)

**“My baby always has food or milk in his/her mouth. Does that matter?”** We can still use the sample even if you wait less than the 20-30 minutes after eating that we request -- or if you cannot wait at all. It is better to wait, even a short time, between feeding your child and collecting the sample so there is nothing in the mouth. However, if that is not possible, you can still collect the sample.

**“What if everyone can’t give the sample at the same time?”** The samples do not need to be collected at the same time. You can collect the samples at different times for yourself, your baby, and/or the baby’s father. (You can wait to mail the samples together, or you may mail in the completed samples and ask for another mailing envelope for the rest of the samples.)

**“What if the father won’t collect his sample, or I don’t want to do it for the baby? Do you still want my sample?”** You can still collect your sample even if the father does not want to participate or if you don’t want to collect the sample for your baby. The samples do not need to be collected for every person. You can collect the samples just for yourself or for yourself and your baby.

**“Will the samples expire? Is there a deadline for completing the sample kits?”** There is a “collect by” date on each collection container. As long as you collect your samples before the “collect by” date, you can send them back to us. There is not another deadline for sending the kits, but it will help us to get the samples as soon as possible. Please let us know if your kit has expired and we can send one more kit to you (but we can’t send more than one replacement kit).

## WHAT HAPPENS TO SAMPLES AFTER I MAIL THEM IN?

**“What happens to the saliva samples?”** First, the genetic material is removed from the saliva samples. Then the genetic material is sent to a place to be stored until researchers are ready to use it for a study.

**“What kinds of tests will be done?”** The goal of our study is to understand the causes of birth defects. Changes in some genes are already thought to be important in the cause of birth defects. We study these genes to learn how changes in them could lead to a birth defect. Other genes are new or have not already been studied in birth defects. Changes in these genes will be tested to see how they might affect birth defects. Many of the gene studies need large numbers of families. In most cases, birth defects are caused by a combination of genes and other factors, such as exposures to certain medications or chemicals in the environment. Because of this, we will learn about the causes of birth defects by examining data from both telephone interviews and gene tests. Often, genetic material will be stored for many years before enough families are available for studies to be done.

**“Will there be publications?”** We will share what we learn with other health professionals through scientific publications. We also will make an e-newsletter available to women who participated in the study. No publications will include information which could identify you or your child in any way.

**“Will I receive the results of the tests or analyses?”** No, you will not receive individual test results. The studies to be performed on these samples are not meant to test the medical status of you or your child. For this reason, we do not plan to return to you the results of the studies. If you have questions about whether any genetic tests would be useful to you, we recommend that you consult your health care provider.

Instead of individual results, we will publish an e-newsletter every year with important study results to all who participate. This e-newsletter will keep families informed of any major findings, especially if the results of our study lead to a gene test. The e-newsletter will be available at the following web address: **insert address**. Families can then talk with their doctor or genetic counselor to help them decide whether a certain gene test could be helpful to them.

**“Why can’t my results be sent to me?”**

There are several reasons why your test results are not sent to you:

*First*, the gene tests that will be done on your samples are for research. This means that our study will look for connections between birth defects and genes. Before these connections can be useful, the studies must be repeated in other labs using samples from other families. Until this is done, we cannot be sure that these connections mean anything to families.

*Second*, while our tests will be carefully done, they will not meet the strict standards that are required for medical gene tests. Since these standards have not been met, we will not send individual test results.

### **RISKS:**

The possible physical risk of this procedure is for temporary, minor discomfort to the inside of the mouth.

### **BENEFITS:**

There is no personal benefit to you for taking part in this study (except the \$20 gift card you received with the kit and the \$20 gift card you will receive after you return the kit). The major benefit is that this study may result in a better understanding of the causes of birth defects.

**CONFIDENTIALITY:**

All information that we gather in this study will be kept confidential. This is assured by a Certificate of Confidentiality that protects your legal rights under the Public Health Service Act (*under section 301[d] of the Public Service Act 42 U.S.C. 241[d]*). The Certificate of Confidentiality prevents study staff from being forced under a court order or other legal action to identify you or anyone else in this study. This protection lasts forever (even after death) for any persons who were subjects in the research during any time the certificate was in effect. However, you should understand that the investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others. Records may be reviewed by officials checking on the quality of the research. Information about you may be shared with other researchers when and if it has been approved by research review committees. This information will be used only for the study of birth defects. We will never use any names in reports or publications. If you would like a copy of the Certificate of Confidentiality for this study, you may call Ms. Kimberly Newsome at (404) 498-4315 and it will be provided to you.

**“Will information be released to my insurance company?”** No, the researchers will never give any of your information, responses, or tests to any insurance company. (Also, your information will not be given to your doctor or any other health care providers.)

**Specific privacy protections at your Center: INTERVIEWERS MAY DESCRIBE DETAILS ABOUT LOCAL CONFIDENTIALITY PROTECTIONS AT YOUR CENTER,** e.g., When we receive your consent form with your names, we separate that form from your samples and store it in a separate locked cabinet.

**COSTS/COMPENSATION:**

Parents who agree to provide saliva samples on themselves and their child will be provided a \$20 gift card to thank them for their time. There is no payment for medical treatment in the unlikely event of injury as a result of taking part in this study.

**“Should I return the \$20 gift card if I don’t complete the kit?”** You may keep the \$20 gift card if you decide not to complete the kit.

**RIGHT TO REFUSE OR WITHDRAW:**

Participation in all parts of this study is voluntary. You and your child are free to not take part in the study and you are free to withdraw from any or all parts of this study at any time without penalty or loss of benefits to you. If at any time in the future you would like to have your interview information or saliva cell samples destroyed or removed from the study, please call Ms. Kimberly Newsome at **(404)-498-4315** at the Centers for Disease Control and Prevention (CDC).

**CONTROL AND OWNERSHIP OF BIOLOGIC MATERIALS:**

**“What will researchers do with the samples?”** Some of the saliva samples will be studied shortly after they are collected. Most of the saliva samples will be stored for studies in the future. Individual results of future studies of stored specimens will not be reported to you or the other participants or their physicians. Study researchers will have control over the stored samples unless you request that your sample be removed from storage. If you wish to have your specimen(s) removed from storage, please contact Ms. Kimberly Newsome at **(404)-498-4315** (at CDC).

**COMMERCIAL VALUE OF BIOLOGIC MATERIALS:**

We will not use the saliva samples collected from you for commercial purposes.



**CONTACTS: If you have any further questions, please contact:**

If you have **questions about genetic testing or counseling**, you may call:

**Dr. Richard Olney, MD**

National Center on Birth Defects and Developmental Disabilities

**1-404-498-4315**

or

**Ms. Kimberly Newsome**

BD-STEPS Study Coordinator

Centers for Disease Control and Prevention

**1-404-498-4315**

If you have **questions about your rights as a subject in this research study**, please call the Office of the Deputy Associate Director for Science for CDC at **1-800-584-8814**; leave a message including your name, phone number, and refer to protocol #2087, and someone will call you back as soon as possible.

If you have specific **questions about how to use the kit or collect the saliva samples**, please call:

Ms. Kimberly Newsome at **1-404-498-4315** (at CDC).